

CRONO *TWIN*

Ambulatory infusion pump





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SYMBOLS AND CONVENTIONS

To assist you in using the manual, the following symbols and conventions have been used:

Triangle containing an exclamation mark

This “**WARNING**” icon indicates something that must always be taken into consideration for the safe use of the pump.




Notepad

This icon indicates a “**NOTE**” containing additional information or useful tips about the use of the pump.



Flashing symbol

The graphic symbol  shown in the manual above the pictures of the pump display, indicates that the information below it is flashing.

This manual is divided into 4 parts:

Part 1 (red): sections 1 to 7, general information, technical specifications and warnings.

Part 2 (blue): sections 8 to 10, which describe the functions of the **CRONO TWIN** device.

Part 3 (orange): section 11, which describe the *reservoir*, the preparation and insertion of the *reservoir* into the pump, the infusion sites and the preparation for an infusion.

Part 4 (purple): sections 12 and 13, giving general warnings and a description of the supplied standard equipment, as well as discussing maintenance, disposal and support. It also details the guarantee and the declaration of conformity.

Appendices: Pages 65 to 77.

INTRODUCTION

Thank you for choosing the **CRONO TWIN** ambulatory infusion pump.

This manual has been prepared to enable you to make the best use of the **CRONO TWIN** pump, supplying information on the settings, safe use and maintenance of the device.

If any of the information is not clear, or if you have any doubts or questions, please contact the Customer Support Service of CANÈ S.p.A.

Incorrect use of the pump, or the failure to follow the instructions and warnings provided in this manual, could cause serious injury.

The instructions provided relate exclusively to the ambulatory infusion pump, model **CRONO TWIN**. They are intended for use by the medical and paramedical personnel who need to set up the pump initially and subsequently by patients who are capable of managing their therapy autonomously, or persons who are caring for patients.

The pump has a settings locking system (see page 24) which stops the settings from being modified by accident. The information relating to the locking/unlocking of the settings lock is supplied at the back of this manual on a plastic card.

The purpose of the settings lock is to avoid accidental or unauthorised modification of the selected parameters. If it is considered inappropriate that the patient should be aware of how to unlock the settings lock, the doctor and/or other person who is assisting the patient should not supply this information.

The instructions in this manual are essential for the safe and correct use of the pump. You are recommended to read the whole manual before starting to use the device and to keep the manual handy for future reference.

The pump does not need to be installed, tested and/or activated.

CANÈ S.p.A. reserves the right to modify the hardware and software specifications described in this manual at any time and without notice.

NOTES



- CANÈ S.p.A. reserves the right to modify and/or update this manual at any time and without notice.
- In order to make this manual as complete and accurate as possible, please report any errors or omissions to the following e-mail address: service@canespa.it.

WARNING: PRECAUTIONS FOR USE



This pump is not recommended for independent use by patients who are unable to follow and understand the instructions supplied in this manual, or unable to perform the basic operations and the regular maintenance of the pump.

INFORMATION

For further information on the **CRONO TWIN** pump, contact:

Customer Support Service

CANÈ S.p.A. Medical Technology

Via Cuornè, 42/a

10098 Rivoli (Turin) - Italy

Tel. +39 011 957 4872

Fax +39 011 959 8880

Internet: www.canespa.it e-mail: service@canespa.it

INTENDED USE

The **CRONO TWIN** ambulatory infusion pump is designed for the subcutaneous infusion of immunoglobulins and drugs in general.

The administration of drugs by other means relieves CANÈ S.p.A. of all liability.

NOTE



The manufacturer holds itself liable for the safety and the correct functioning of the device, provided that it is used in accordance with these instructions and that any required repairs and/or modifications are carried out exclusively by the said manufacturer.

WARNINGS



The use of incorrect settings and/or incomplete understanding of the operational functionality and of the alarms could cause serious harm to the patient.

Before using the pump, evaluate whether its use is appropriate for the need and for the patient, paying close attention to the following aspects:

- The technical specifications of the pump
- The infusion sets which will be used
- Whether you will be using multiple tube sets and clamps *in the* infusion line
- The cognitive and psycho-physical condition of the patient.

With respect to the clinical procedural aspects, which are the responsibility of the medical or paramedical personnel, the above list is supplied for example purposes only and is not exhaustive.

The device must be used:

- Under medical supervision
- Adopting appropriate procedures and adequate measures when dealing with patients who could suffer serious consequences (injury or death) in the event of accidents and/or breakdowns which cause an interruption of the administration of the drug.

Do not prime the infusion line when it is connected to the patient, because this could cause an overdose of the drug.

Before beginning an infusion, inspect the fluid path to ensure there are no folds, clamps, or other occlusions in the line, and expel any air bubbles.

The level of precision and amount of time needed to detect an occlusion could differ from the values indicated in this manual, depending on the type of catheter, the infusion set and all the elements which comprise the infusion line.

If you have any suspicion that the pump has been in any way damaged, for example by fluid penetration or having been dropped, contact the Customer Support Service to check that the pump is functioning correctly. Do not use a damaged pump.

If you have any doubts about the functioning of the pump and/or an error or anomaly occurs, stop using the device and contact the Customer Support Service.

CANÈ S.p.A. does not supply a replacement service for the pump during the period needed for any repairs; such service should be supplied by the relevant medical structure or the local distributor.

Any liquid on the pump casing must be removed immediately with absorbent paper.

It is important to establish a procedure and/or alternative to pumped infusion, in case the pump malfunctions. A valid alternative could be to have both a second pump and an alternative backup system.

It is recommended that the people who assist and/or live with the pump user know how the pump works and are aware of the information in this user manual.

It is important to stop using the device after the indicated service life has expired and follow the instructions for its correct disposal.

Do not administer immunoglobulins intravenously; if they are accidentally administered to a blood vessel or capillary the patient could suffer an anaphylactic shock or thromboembolic events. Always check this before continuing with an infusion.

PUMP DESCRIPTION

CRONO TWIN is an ambulatory infusion pump which uses single-use *reservoirs* for the controlled subcutaneous administration of immunoglobulins.

CRONO TWIN uses specific 20 ml syringes called *reservoirs*.

Its smaller size and reduced weight make **CRONO TWIN** ideal for home use, thus giving the patient the freedom to engage in everyday activities during the therapy.

The main technical feature of the pump is that it uses two 20 ml *reservoirs*, thereby allowing 40 ml of a given drug to be administered at the same time and in equal amounts at two different infusion sites.

The pusher mechanism acts directly on the pistons of the *reservoir*, allowing the pump to administer the drug accurately.

One of the pump's standout features is the ability to choose between time or flow rate programming modes.

For a better absorption of the drug, the pump administers 9 µl shots (per infusion site) at intervals which depend on the duration of the infusion or the flow rate chosen. If the infusion duration is reduced or the programmed flow rate is increased, the time interval between the shots decreases proportionally.

CRONO TWIN has a liquid crystal display (LCD) which provides the doctor and the patient with information about the settings, operations and diagnostics of the pump.

TECHNICAL CHARACTERISTICS

Pump dimensions	81 x 82 x 33 mm (3.18 x 3.23 x 1.31 in).
Weight	158 g (5.57 oz.), including battery.
Battery	Lithium CR 123A 3V (battery life of about 100 infusions).
<i>Dedicated single use reservoir</i>	with a 20 ml capacity and a “Luer-Lock” universal security attachment.
Partial volume	May be selected, from 1 to 40 ml in 1 ml increments.
Time mode	Can be programmed from: <ul style="list-style-type: none"> • 30 minutes to 2 hours in 5 minute increments. • 2 hours to 24 hours in 15 minute increments. • 24 hours to 400 hours in 2 hour increments.
Flow rate mode	Can be programmed from: <ul style="list-style-type: none"> • 0.1 ml/h to 1.00 ml/h in 0.01 ml/h increments • 1.00 ml/h to 10 ml/h in 0.1 ml/h increments • 10 ml/h to 100 ml/h in 1 ml/h increments
Volume of priming available	3 ml.
Flow rate precision	+/-2%.
Occlusion pressure	5.5 bar +/- 2.5
Shot volume	9 microlitres.
Occlusion signaling time	See APPENDIX 4.
Post-occlusion bolus	About 1.0 ml.

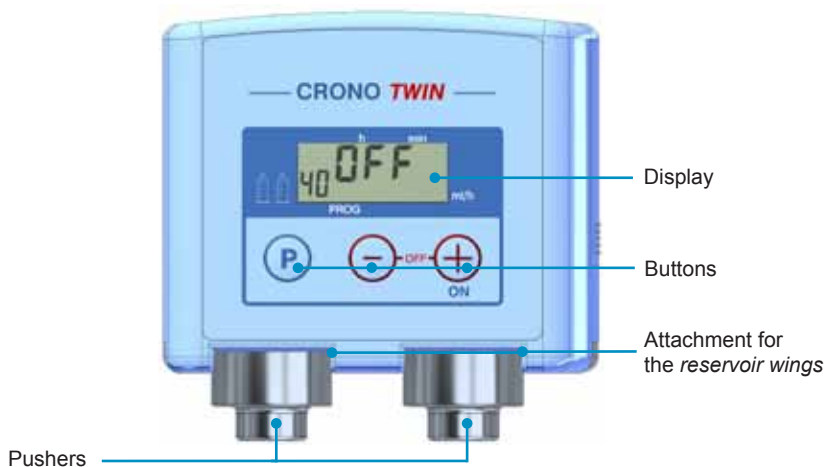
Electronic circuit	Managed by twin microcontrollers with dedicated software.
Settings memory	All settings are automatically stored in a flash memory which is retained even if the device is left without a battery.
Display	Liquid Crystal Display (LCD) (dimensions 1.1 x 2.8 cm; 0.43 x 1.0 in).
Motor	Coreless DC Motor. The microcontroller controls the rotation speed using an infrared encoder.
Settings lock	Two configurable levels.
Twin microcontrollers	Guarantee a more reliable system.
Safety circuits	These check that the device is functioning correctly, intervening in the event of any anomaly with sounds and messages on the display.
Protection rating	IP 4X
Pump operating conditions	+10°C / +45°C. 30% / 75% RH. 700 hPa / 1060 hPa.
Pump storage conditions	-10°C / +60°C. 10% / 85% RH. 500 hPa / 1060 hPa.

SUPPLIED STANDARD EQUIPMENT

1. **CRONO TWIN** ambulatory infusion pump with *reservoir*.
2. Ambulatory infusion pump carry-case (Code: VAL/01R).
3. Elastic belt (Code: CM/01).
4. Leatherette pouch (Code: CM/30).
5. Pouch support cord (Code: CM/18).
6. 2 Batteries (one of which is already inserted in the pump) (Code: CR/123A).
7. User Manual.

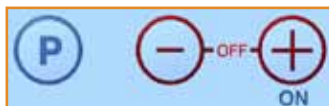


PUMP PARTS



CONTROL BUTTONS

There are 3 control buttons.



The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect. Use only your fingertips; do not use sharp objects.

The buttons make a ticking sound when pressed.

A brief beep confirms that a command is being executed.

WARNING



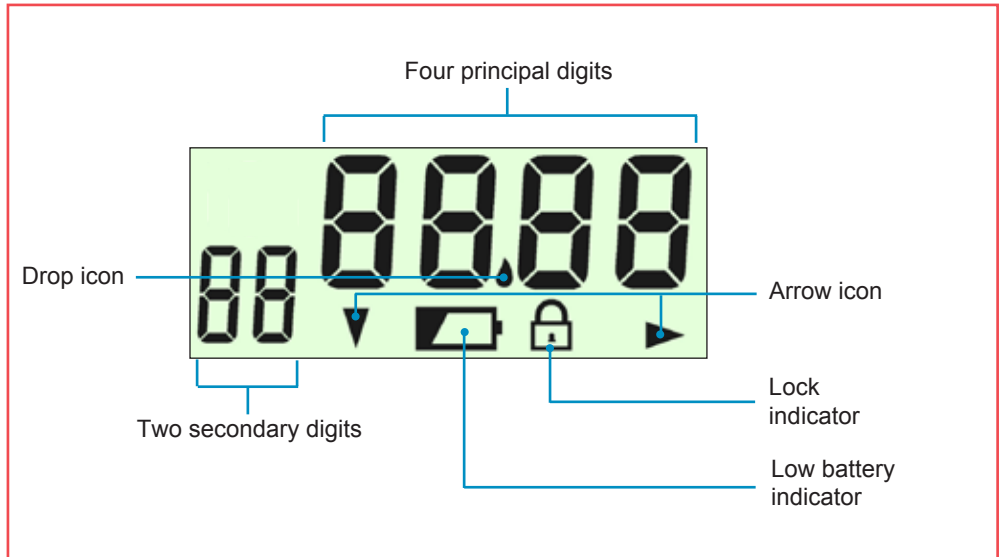
The buttons have different functions according to which of the following states the pump is in when they are pressed:

- **OFF**
- **StoP**
- **ON**

The functions of the buttons in the various different states mentioned above are described in the quick reference instructions on pages 30-32 and in Section 10.

LIQUID CRYSTAL DISPLAY (LCD)

The liquid crystal display uses text messages and icons to display useful information about the settings, the operation being performed and any error situations.



Four principal digits of the display

Display principal information related to the values of the settings, error information, etc.



Two secondary digits of the display

Display:

- The volume of the *reservoir*;
- Information related to the setting being displayed in the four principal digits
- The unit of measurement of the setting being displayed.



“Low Battery” indicator:

Displayed when the battery is nearly spent (see related section on page 21).



“Drop” icon:

Steady: the decimal point indicator.

Flashing: the hour and minute separator.



“Arrow” icon:

- A downward arrow indicates that the pump is being programmed.

- A right arrow indicates that the setting shown is expressed in ml/h.



Minute indicator

Flashes when the remaining duration of an infusion is expressed in minutes (time left is less than 60 minutes).



“Lock” indicator:

Indicates that the settings are locked (**L1**); i.e. they can be viewed but cannot be changed.

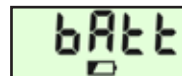


LOW BATTERY ALERT

The appearance of the “**LOW BATTERY**” alert (not flashing) on the display indicates that the battery is low.

If the alert remains displayed for several consecutive infusions, the “**SPENT BATTERY**” message is displayed, accompanied by a beep repeated approximately every 10 seconds.

In these circumstances the pump can no longer be used and the battery must be replaced.



WARNINGS

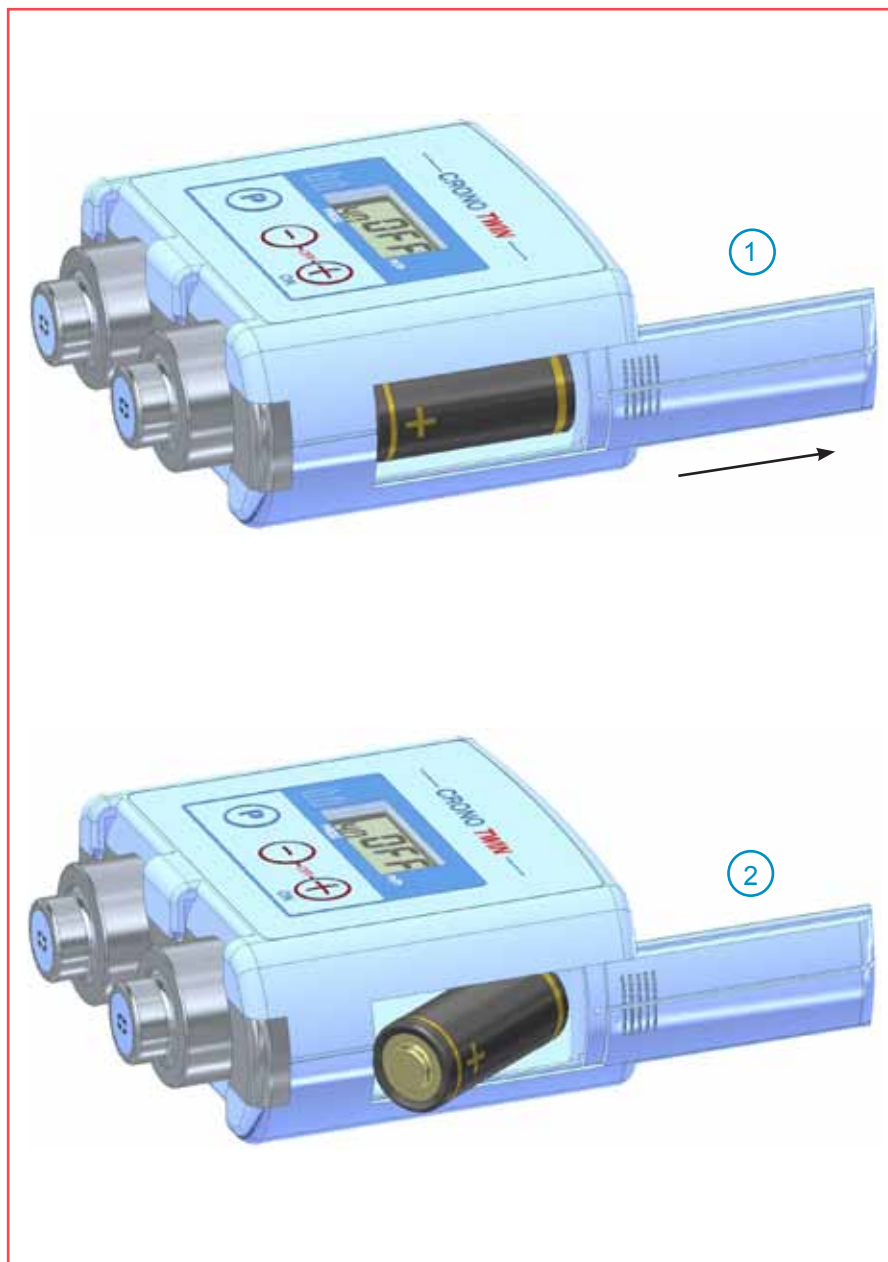


- You are advised to replace the battery after the “**LOW BATTERY**” alert is displayed.
- The battery must not be replaced:
 - during an infusion
 - with the infusion set connected to the patient.
- Use 3 Volt Lithium batteries, model CR 123 A.

BATTERY REPLACEMENT

To replace the battery, ensure that the pump is switched off (the display shows **OFF** or **StoP**), and then proceed as follows:

1. Open the cover of the battery compartment, sliding it off as shown in figure 1 on page 22;
2. Remove the battery, 'positive' end first, tilting it as shown in figure 2 on page 22;
3. Insert the new battery, taking care to ensure that it is the right way up (+ and - poles match up);
4. Close the cover.



NOTES



- After you have inserted the battery, the pump runs an auto diagnosis during which it will emit brief audio signals and display all of the icons and indicators.
- During the battery replacement, the pump retains the current settings in its memory.
- When you have finished changing the battery, check that the compartment is properly closed.

WARNINGS





- Do not use rechargeable batteries.
- Using other types of battery than lithium CR 123 batteries could cause the pump to malfunction.
- The battery life can be influenced by the age of the battery and the temperature and circumstances of its use and storage.
- Ensure you always have a replacement battery available for use.
- If the pump is left inactive for long periods (1-2 months or more), you are advised to remove the battery.

SETTINGS LOCK

The **CRONO TWIN** pump has 2 access configurations:

- **L0 (unlocked)**: in this configuration you can use the control buttons to access all of the settings and parameters and control all of the operational functions.

- **L1 (locked)**: in this configuration you can use the control buttons to control the operational functions but cannot modify any of the settings. When the pump is set to **L1** the display shows the "lock" indicator .

Before attempting to modify any of the settings, ensure that the selected access level of the pump is **L0** (indicator not  displayed).

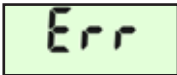
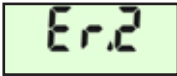

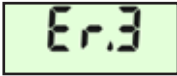

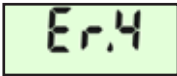
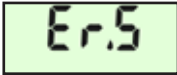

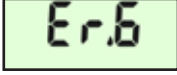
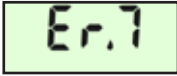



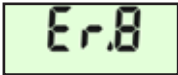
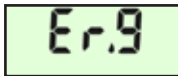
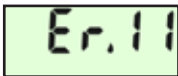
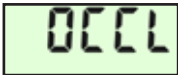

WARNINGS



- This settings access level remains in memory even if the battery is removed.
- When the settings access is **L1** (locked), any attempt to access the locked options will cause the pump to beep and the "lock" indicator on the display to flash.
- The information relating to the locking/unlocking of the settings lock is supplied at the back of this manual on a plastic card and is only for use by a doctor.

ERRORS AND ANOMALIES

DISPLAY	ACOUSTIC SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
	Brief beep.	Operation not allowed	---
	Continuous acoustic signal.	Critical problem in the safety system.	Press the  button.
	Beep repeated every 10 secs. approx.	Anomaly in the motor circuit.	Press the  button.
	Beep repeated every 10 secs. approx.	Mechanism of the pushers blocked while withdrawing (could be caused by a foreign body preventing its movement).	Eliminate the cause and initialise the pump.
	Beep repeated every 10 secs. approx.	Anomaly in the pushers mechanism.	Press the  button.
	Beep repeated every 10 secs. approx.	Anomaly in motor.	Initialise the pump.
	Beep repeated every 10 secs. approx.	Communication error between the two microcontrollers.	Press the  button.

DISPLAY	AUDIBLE SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
	Beep repeated every 10 secs. approx.	When a battery is inserted and at the start of every infusion the pump performs a check of the settings in the memory. If an error is found, the value in error is replaced by the default value, the pump motor is locked and the error is indicated both on the display and audibly.	Initialise the pump.
	Beep repeated every 10 secs. approx.	A check is performed to ensure that the safety circuit which drives the pump motor is working correctly. If an error is found, the pump locks and the error is indicated.	Initialise the pump.
	Beep repeated every 10 secs. approx.	Anomaly in the pusher mechanism.	Initialise the pump.
	Beep repeated every 10 secs. approx.	Mechanism blocked because of an occlusion in the infusion line.	Eliminate the cause and press the  button. See page 28

WARNING



Following the display of error message **Er,8** and the successive initialisation, the system reverts to the factory settings (see page 29): if this happens, the pump settings prescribed by the doctor **should be re-entered**.

NOTES




- The displayed error messages (from **Er,2** to **Er,11** and **OCCL**) are accompanied by a beep and the system stops.
- To initialise the device, remove the battery and reinsert it after 10-15 seconds. If the error is detected again after the corrective action or initialisation of the device, contact the Technical Support Service.

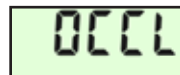
INFUSION SET OCCLUSION

The pump is designed to recognize when the administration of a drug has been interrupted by external means, such as, for example, the kinking of the infusion set tube and consequent occlusion.

An occlusion can be resolved in two ways:

1 - automatically by the pump, which attempts to continue every two minutes;

2 - if the pump's automatic attempts do not work, you must intervene and remove whatever was causing the occlusion. Then re-start the infusion manually by pressing the  button.



An occlusion will normally only affect one of the two infusion lines; the occluded line is easy to identify by looking at the syringes: in the occluded line, the piston will be compressed and the support rings will be more visible and more marked than those in the non-occluded line.

NOTES



- The cause of the occlusion should be looked for along the path of the drug within the infusion set and at the point at which the set is inserted in the patient.
- To avoid or reduce the incidence of occlusions, you are advised to use an infusion set with *anti-kinking* tubes.

POST-OCCLUSION BOLUS

The occlusion alarm is given when the pump detects excessive back pressure in the infusion line. This back pressure must be removed without accidentally releasing a post-occlusion bolus, which could cause serious harm to the patient. The volume of a **CRONO TWIN** post-occlusion bolus, considering only the combined volume of the pump and the *reservoir*, is about 1.3 ml (per reservoir).

WARNINGS



- The volume of the bolus released after an occlusion can vary, depending on the type of catheter, the infusion set and all the other components that comprise the infusion line.
- Another element that could affect the volume of the released bolus after an occlusion is the presence of any air in the system.
- After the occlusion alarm is given, disconnect the infusion set from the patient to avoid a post-occlusion bolus being administered to the patient.

FACTORY SETTINGS

The pump is supplied in **time mode** with the following default settings:

Delivery time	10 h
End of infusion acoustic signal	AL on (active)
Volume	40 ml (in 2 x 20 ml syringes)
Lock level set	L0 (unlocked)
Number of infusions	0




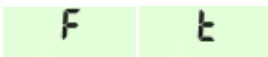


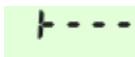
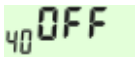
In **flow rate mode** the pump is supplied with the following settings:

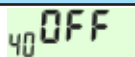

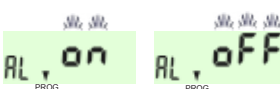


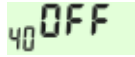


Flow rate	4 ml/h
End of infusion acoustic signal	AL on (active)
Volume	40 ml (in 2 x 20 ml syringes)
Lock level set	L0 (unlocked)
Number of infusions	0






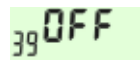
QUICK REFERENCE








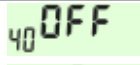
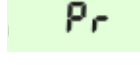
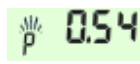


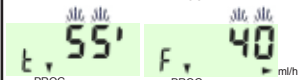

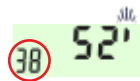
The buttons have a built-in safety timer: you must keep them pressed for several seconds before the command takes effect.




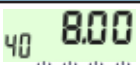
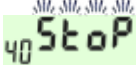
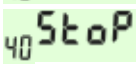
These quick reference instructions are not an alternative to reading the information in this manual, but give a basic and rapid summary of the pump's functions.






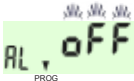


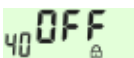
	BUTTONS	ACTIVATION	DISPLAY
BATTERY INSERTION		<ul style="list-style-type: none"> • Self-diagnosis test 	
		<ul style="list-style-type: none"> • Show the type of programme set (flow rate/delivery time) 	
		<ul style="list-style-type: none"> • Access the flow rate/delivery time selection (only possible with L0 access level) 	
		<ul style="list-style-type: none"> • Change the flow rate/delivery time setting 	
		<ul style="list-style-type: none"> • Automatic positioning of the pushers at the start of the infusion 	
		<ul style="list-style-type: none"> • Automatic switch off 	

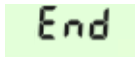
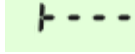
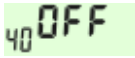
	BUTTONS	SETTINGS	DISPLAY
OFF CONDITION		<ul style="list-style-type: none"> • OFF condition 	
	 1ª pressure	<ul style="list-style-type: none"> • Activate/de-activate end infusion acoustic signal 	
	 2ª pressure	<ul style="list-style-type: none"> • Partial volume programming *1 	
		<ul style="list-style-type: none"> • Pump set to OFF 	
	 / 	<ul style="list-style-type: none"> • Change the value of the preceding settings 	

	BUTTONS	*1 SETTING THE PARTIAL VOLUME	DISPLAY
OFF CONDITION	 / 	<ul style="list-style-type: none"> Partial volume programming Decrease/increase partial volume Positioning the pushers for the partial volume Automatic switch OFF 	   

	BUTTONS	SWITCHING ON	DISPLAY
ON CONDITION	  (keep pressed)    /  	<ul style="list-style-type: none"> OFF condition Priming function Priming administration (3.00 ml available) Switching on the pump Delivery time or flow rate setting Decreasing/Increasing flow rate/delivery time Switch between programmed flow rate/infusion duration display (only if F is selected). During the infusion the two secondary display digits will show the remaining volume to be infused 	       

	BUTTONS	OFF/StoP SWITCH	DISPLAY
ON CONDITION	 +  	<ul style="list-style-type: none"> Programmed delivery time StoP condition Silence acoustic signal and flashing display 	  

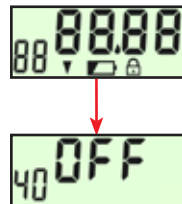
	BUTTONS	SCROLLING SETTINGS	DISPLAY
OFF/StoP CONDITION	<div> 1ª pressure</div> <div> 2ª pressure</div>	<ul style="list-style-type: none">• OFF/StoP condition• End of infusion acoustic setting• Programmed partial volume• OFF/StoP condition	<div></div> <div></div> <div></div> <div></div>

	BUTTONS	END OF INFUSION	DISPLAY
END OF THE INFUSION		<ul style="list-style-type: none">• End of the infusion• Automatic repositioning of the pushers to the starting position• Automatic switch-off	<div></div> <div></div> <div></div>

PUMP INITIALISATION

When you insert the battery, the pump runs the initialisation sequence, during which it:

1. Runs an auto-diagnosis, emitting a series of short beeps and displaying all the indicators and icons on the display.
2. Displays **OFF** at the end of the preceding operation.



NOTES



- The pump is supplied pre-loaded with a battery.
- For instructions on how to install the battery, see page 21.
- You are advised to initialise the pump if it is left unused for a long period (more than 1 - 2 months) and the battery is not removed.
- If, after the insertion of the battery (initialisation of the pump), the display does not indicate the above mentioned information you should remove and re-insert the battery.

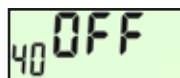
PUMP SETTINGS SEQUENCE

Upon inserting the batteries, you can choose the way in which the pump is programmed:

- 1 - by flow rate, expressed in ml/h (**F**) or,
- 2 - in time, expressed in hours and minutes (**t**).

Procedure

- 1 - Remove and re-insert the battery.
- 2 - The display shows all the symbols.
- 3 - At the same time, the device carries out an auto-diagnosis during which it emits a beeping sound.
- 4 - The display will then show the programming mode **F** (flow rate) or **t** (time): pressing the **P** button makes the symbol flash; you can move from one option to the other using the **-** or **+** buttons.
- 5 - Not pressing these buttons for 4 seconds will cause the device to memorise the mode that has been selected.
- 6 - The pump then mechanically positions the pushers for the start of the infusion and the display reads **OFF**.



NOTE



Setting the programming mode is only possible with **L0** access.

WARNING




Choosing whether to programme the pump by flow rate or by time is the responsibility of the doctor, who will decide on the most suitable method.



SETTINGS IN OFF CONDITION

When the device is set to **OFF**, the following parameters can be set:

- 1 - End of infusion acoustic signal (programmable also in **StoP** condition);
- 2 - Partial volume.

The parameters can only be selected if the pump has its settings unlocked (**L0**).

To access the pump settings sequence while the device is in the **OFF** state, you need to press the  button.

You can change the setting while the display is flashing using the  and  buttons.



NOTES



- The settings of the end of acoustic signal, the flow rate or the delivery time and the partial volume is only possible when the keyboard is unlocked (**L0**).
- When the settings lock is on (**L1**), if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.
- The partial does volume can only be programmed at the start of a new infusion.

1 - END OF INFUSION ACOUSTIC SIGNAL

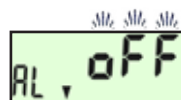
1. In the **OFF** or **StoP** state, by pressing the **P** button: the pump enters the mode for selecting the end of infusion alarm.

2. When the **off** or **on** icon flashes, the selection can be made using the **-** and **+** buttons.

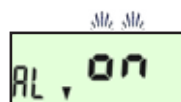
Selecting **off** disables the end of infusion signal; selecting **on** activates the end of infusion signal, which will sound 5 mins and 10 mins before the end of the infusion.

3. Do not press any button for 5 seconds, and the setting phase will end. The displayed value stops flashing and then the **OFF** or **StoP** indication is displayed.

4. By pressing the **P** button before the **OFF** or **StoP** button appears (while the **OFF** or **On** indication is flashing) you move to the next parameter: **SETTING THE PARTIAL VOLUME**.



PROG



PROG



PROG

NOTES



- When the settings lock is on (**L1**), if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.
- In the **StoP** condition, after the setting for the acoustic alarm at end of infusion, the display shows the current partial volume setting but does not allow it to be changed. Instead **Err** is shown on the display if the **P** button is pressed.

2 - SETTING THE PARTIAL VOLUME

The partial volume function is used when the therapy requires an infusion with a dose of less than 40 ml.

The partial volume can be set from 1 cc to 40 cc in increments of 1 cc.

You can set this parameter by pressing the **P** button again after programming the end of infusion acoustic signal.

The partial volume function can only be set before the start of a new infusion, either partial or complete (40 ml).

Proceed as follows:

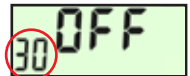
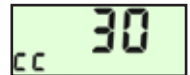
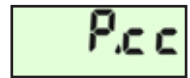
1. The display shows a flashing value for the volume, preceded by **cc**, which indicates the unit of volume (1 cc = 1 ml).

2. Press the **-** button to decrease the value, and the **+** button to increase it. Each change is indicated by a beep.

3. Do not press any button for 5 seconds and the setting phase will end; the display will show **P,cc**.

4. The pump moves the pushers to the position which corresponds to the set volume, giving an intermittent beep while it does so, and displaying -- in real time -- the actual volume corresponding to the pushers position.




5. When the pushers is in the correct position the display shows **OFF**.



NOTES



- The partial volume setting is automatically stored in the pump's memory.
- At the end of the infusion, the pushers returns to the position corresponding to the partial volume setting.


- Each time an infusion is started or restarted the display shows the current partial volume setting.
- The partial volume setting can be interrupted by pressing the  and  buttons: the pump switches off (the display shows **StoP**) and the pushers, if they were moving forward, remain where they were when the interruption occurred. The partial volume setting is not stored and the previous value remains in force. However, if the pushers were withdrawing the display toggles between **StoP** and **P,cc**. The only possible operation is to continue the withdrawal of the pushers, by pressing the  button. The pushers withdraw to the position of the partial volume setting.

WARNINGS



- This operation must not be carried out with the infusion set connected to the patient.
- A partial volume cannot be set while an infusion is in progress.
- The partial volume setting remains in the pump's memory even if the battery is removed.
- If the battery is removed when the pump is set to **OFF/StoP**, the partial volume remains in memory and the pushers is not withdrawn.
- If the battery is removed when the pump is set to **ON**, the pushers returns to the infusion start position to recalibrate itself and is then repositioned at the stored partial volume.

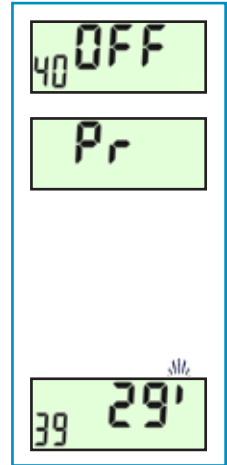
SWITCHING ON THE PUMP

From the **OFF** state, press the  button. The pump will give a brief beep and display:

- **Pr** (priming *function*); the display shows **Pr**.

There are three options:

- Postpone the *priming*.
 - Skip the *priming*.
 - Carry out the *priming*.
- Having carried out the *priming*, or if the pump is turned on to resume the infusion from the **StoP** state, the display will show the infusion duration.




PRIMING THE INFUSION SET TUBE

The priming function lets you fill the infusion set tube with the drug contained in the reservoir.

The volume available for *priming* is 3.0 ml (1.5 ml per infusion set), which may be dispensed in 1 ml fractions.

The priming function is enabled when you switch on the device and the pushers are in the infusion start position, regardless of whether the settings lock is on.

The priming procedure is as follows:


- Turn on the device by pressing the  button.
- The display shows **Pr**. There are three options:

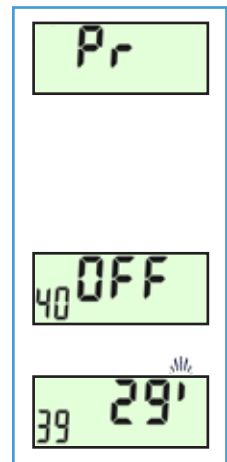
- Postpone the *priming*.
- Skip the *priming*.
- Carry out the *priming*.

a. Postpone the *priming*


Wait 10 seconds, the pump will turn off automatically.

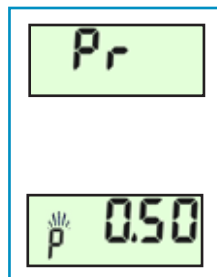
b. Skip the *priming*

Press the  button: the pump starts the infusion and the display shows the time remaining until the end of the infusion, or the current flow rate.



c. Carry out the *priming*


Press and hold the  button: the pump delivers the priming dose until you release the button, and the display shows a flashing letter **P** in the secondary digits followed by the number of ml delivered. When the button is released, the display shows **Pr** again. The maximum volume that can be delivered is 1 ml and the procedure can be repeated for up to a total of 3.0 ml (1.5 ml per infusion set).



Proceed until the infusion set is completely full and a few drops of the drug leak out of it.

There are no time limits to the priming operation.

NOTES

- If, after the priming indication is displayed, the buttons are not pressed again for 10 seconds, the display shows **OFF**.
- The priming function can be interrupted by releasing the  button. The display shows **Pr** again, and you again have the choice of postponing, cancelling or performing the priming function as described above.

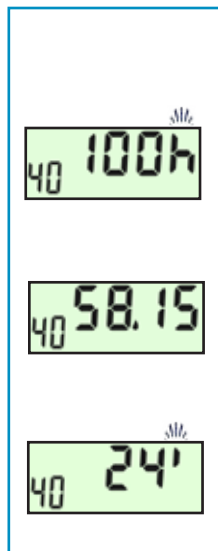
WARNINGS


- Do not prime the infusion set with the tube connected to the patient.
- The priming function must only be performed with the *reservoir* attached to the infusion set and before inserting the needle into the infusion site.
- Before beginning an infusion, check that there are no air bubbles in the infusion line, expelling any that are found. Alternatively, use a vented filter.

THE PUMP IN ON CONDITION

When the pump is in **ON**, the display shows the duration of the infusion in three different ways:

- when the delivery time is equal or greater than 100 hours, the display shows a flashing letter **h** and the time will fall hour by hour.
- when the delivery time is less than 100 hours, the display will show the infusion duration in hours and minutes separated by the flashing 'drop' icon; the time will count down minute by minute.
- if the delivery time is less than one hour, the time is shown in minutes, and the flashing “**minutes to go**” symbol is displayed.



If the pump is programmed according to flow rate, by pressing the  button you can move from a display of the delivery time to a display of the programmed flow rate (with a flashing right arrow and showing the ml/h unit of measure) and back again.

WARNINGS



Before starting an infusion:

- Inspect the fluid path to ensure there are no folds, clamps, or other occlusions in the line
- Expel any air bubbles.

SETTINGS IN ON CONDITION

In the **ON** condition it is possible to set the following parameters:

- 1 - Delivery time** (if time mode was selected when the battery was inserted).
- 2 - Flow rate** (if flow mode was selected when the battery was inserted).

1 - SETTING THE DELIVERY TIME



This function is only available if the “t” function (infusion duration) is selected when inserting the battery.

The delivery time can be set from 30 minutes to 400 hours as follows:

- From 30 minutes to 2 hours in increments of 5 minutes
- From 2 hours to 24 hours in increments of 15 minutes
- From 24 hours to 400 hours in increments of 2 minutes.

Procedure:

1. Press the  button to programme the parameter:
SETTING THE DELIVERY TIME.



2. Press the  button to decrease the value, and the  button to increase it.

3. Do not press any button for 5 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then the remaining infusion duration is displayed.



NOTES



- If you keep pressing either the  or the  buttons, it is possible to change the infusion duration quickly.
- When the settings lock is on (**L1**), if any attempts are made to change the parameter then the display will show the flashing lock symbol and the device will beep several times.
- The partial volume can only be programmed at the start of a new infusion.


2 - SETTING THE FLOW RATE



This function is only available if the “F” function (flow rate) is selected when inserting the battery.

The flow rate can be set from 0.1 ml/h to 100 ml/h as follows:

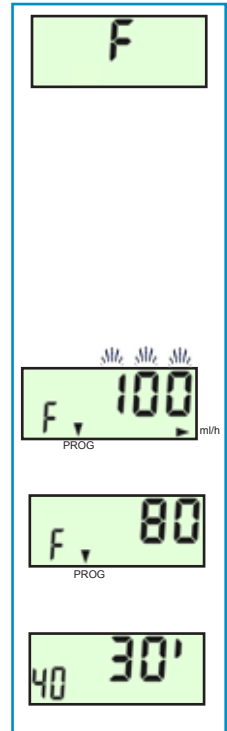
- From 0.1 ml/h to 1.00 ml/h in increments of 0.01 ml/h.
- From 1.00 ml/h to 10 ml/h in increments of 0.1 ml/h.
- From 10 ml/h to 100 ml/h in increments of 1 ml/h.

Procedure:

1. Press the  button to programme the parameter: **SETTING THE FLOW RATE.**



2. Press the  button to decrease the value, and the  button to increase it.

3. Do not press any button for 5 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then the remaining infusion duration or flow rate is displayed.



NOTES



- If you keep pressing either the  or the  button, it is possible to change the flow rate quickly.
- When the settings lock is on (L1), if any attempts are made to change the parameter then the display will show the flashing lock symbol and the device will beep several times.

END OF THE INFUSION

Ten minutes before the end of the infusion, the device gives an intermittent beep lasting 2 seconds. This signal is repeated twice at 5 minutes from the end of the infusion.

At the end of the infusion a continuous signal is given and the display shows **End** (only if **AL** is **on**).

A rectangular display with a green background and a black border, showing the word "End" in a black, pixelated font.

After a few seconds, the pushers start withdrawing until they reach the start position of the infusion.

When the withdrawal is complete, the display shows **OFF** and the pump is ready for a further infusion.

A rectangular display with a green background and a black border, showing the text "1- - -" in a black, pixelated font.

If **AL** is set in **oFF** no end of infusion acoustic signals are emitted during the infusion.

A rectangular display with a green background and a black border, showing the text "40 OFF" in a black, pixelated font.

NOTE









The withdrawal time for a 40 cc syringe is about 6 minutes and is proportionately less for lower volumes.

WITHDRAWING THE PUSHERS

1. Stopping an active infusion before the end

This function allows you to interrupt an active infusion, withdrawing the pushers to the start position of the infusion.

To carry out a withdrawal, proceed as follows:

- Turn off the pump by pressing simultaneously on the  and  buttons.
- Press the  and  buttons together: the display shows **End** for 10 seconds and then begins to withdraw the pushers.
- During the 10 seconds that the display shows **End** you can cancel the withdrawal request by pressing the  and  buttons together.

2. Withdrawal of the pushers at the end of the infusion

At the end of the infusion the display shows the message **End** and the infusor will emit a continuous sound for a few seconds.

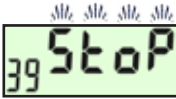
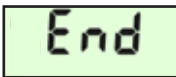
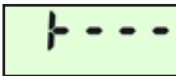
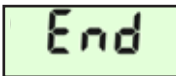
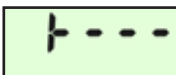
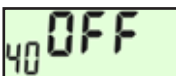
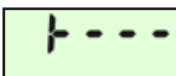
The pushers will remain stationary at the end-infusion position for around 10 seconds, after which they will begin to withdraw until they reach the start-infusion position.

After a few seconds, the pushers start withdrawing until they reach the start position of the infusion.




When the withdrawal is complete, the display shows **OFF** and the pump is ready for a further infusion.

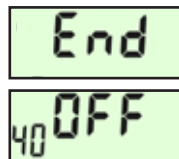
Pushers in motion

While the pushers are in a continuous withdrawal motion, the display shows the “**pushers continuous withdrawal**” indicator.



NOTE


Pusher withdrawal at the end of infusion can be interrupted by pressing the  and  buttons together. The display then toggles between **End** and **OFF**. At this point the only active button is the  button. When you press it the pump recommences the withdrawal of the pushers.

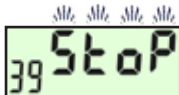
**WARNING**

Do not remove the *reservoir* until the pushers reach the infusion-start position.

SWITCHING OFF THE PUMP

To switch off the pump during an infusion, press the  and the  buttons together; the display will show **StoP**.

If the pump is switched off during an infusion, the device will emit a series of 10 short beeps every 10 seconds, and the display will flash the **StoP** message. To interrupt the audible signals, press the  button. These indications will be repeated each time the pump is switched off during an infusion.





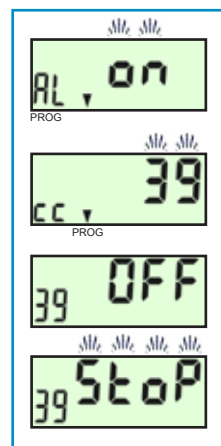
DISPLAYING THE SETTINGS

This function displays the currently programmed settings of the pump. To display the pump settings, the pump must be set to **OFF** or **StoP**.

If the settings are displayed when the settings lock is set to **L0** (settings lock off) the settings flash and can be modified (acoustic alarm only, if the pump is in **StoP**). If the settings are displayed when the settings lock is set to **L1** (settings lock on, with the display showing the "lock" indicator), the settings do not flash and cannot be modified.


The procedure is as follows:

1. Press the button  for approximately one second: the display shows the selection of the acoustic alarm at end of infusion;
2. Pressing the  button again shows the preprogrammed partial volume;
3. If no button is pressed for approximately 5 seconds the display returns to **OFF** or **StoP**.



VISUALIZING PARAMETERS WHEN THE PUMP IS IN THE ON CONDITION


This function allows checking the current flow setting of the pump.

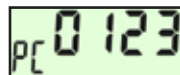
To show the current flow setting the pump must be in **ON**. If the pump is in flow mode, pressing the button  will cause the display to alternate between showing the infusion duration and the flow setting (shown with the right arrow flashing to indicate that the value is in ml/h).



RESETTING THE NUMBER OF PARTIAL INFUSIONS

The device contains two infusion counters: one which is partial and can be reset and another which shows the total number.

To reset the number of partial infusions, proceed as follows:

1 - Press the  button for about 5 seconds, until the display shows the number of partial infusions.






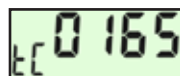
2 - Without releasing the  button, press the  button and the **PC** (Partial Counter) will appear on the display with the number of partial infusions shown in flashing numbers.




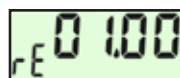
3 - By pressing the  button once more you can enter the programming phase (indicated by the downwards arrow).




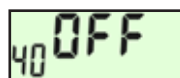
4 - By pressing the  or  button you can reset the number of partial infusions, while pressing the  button once more you can see the total number of infusions **tC** (Total Counter).



5 - By pressing the  button once again, you can see the firmware version of the pump.



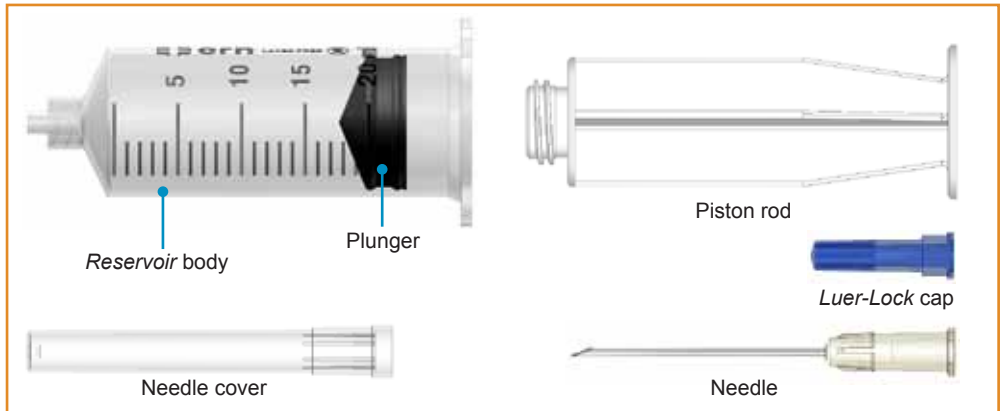
6 - If you do not press anything for 7 seconds or press the  button once more, the display will switch to read **OFF**.



RESERVOIR PARTS

The **CRONO TWIN** pump uses dedicated 20 ml *reservoirs*, model: CRN® CRONO® Syringe.

The *reservoirs* are: single-use, non-pyrogenic and only to be used if the packaging is intact.



WARNINGS



- For safety reasons, you are recommended to use the original CRN® Crono® *Reservoir*.
- The use of any other type of reservoir *could damage the pump and harm the patient*.
- CANÈ S.p.A. disclaims all liability if the device is used with a non-original reservoir different from that recommended.

LUER-LOCK CAP FUNCTIONS

- After the *reservoir* has been filled, it facilitates the unscrewing of the piston rod, avoiding spillage of the drug.
- It facilitates the correct connection between the pump pushers and the rubber piston of the *reservoir*.
- It protects the drug inside the *reservoir* in case it is not used immediately.

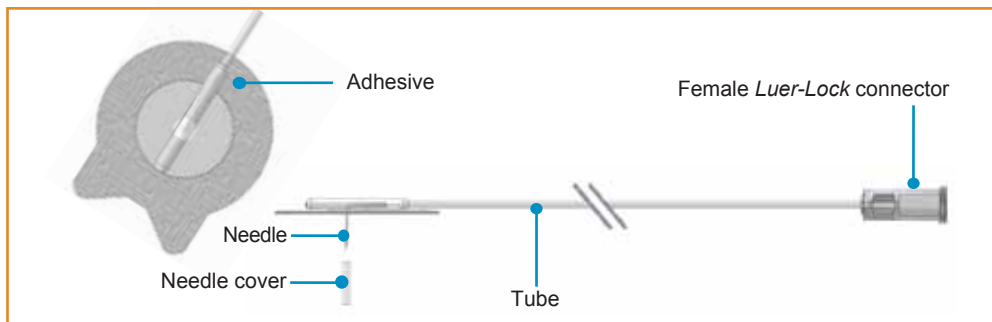


INFUSION SET

You are recommended to use an infusion set with the following characteristics:

- Internal volume of reduced tube (ideal 0.1 ml, maximum 0.62 ml);
- Tube length not more than 90 cm;
- Anti-kink tubing.

INFUSION SET PARTS



NOTE



The images show the Neria™ infusion set from Unomedical, a company of the Convatec group.

PREPARATION OF THE *RESERVOIRS* AND INSERTION INTO THE PUMP

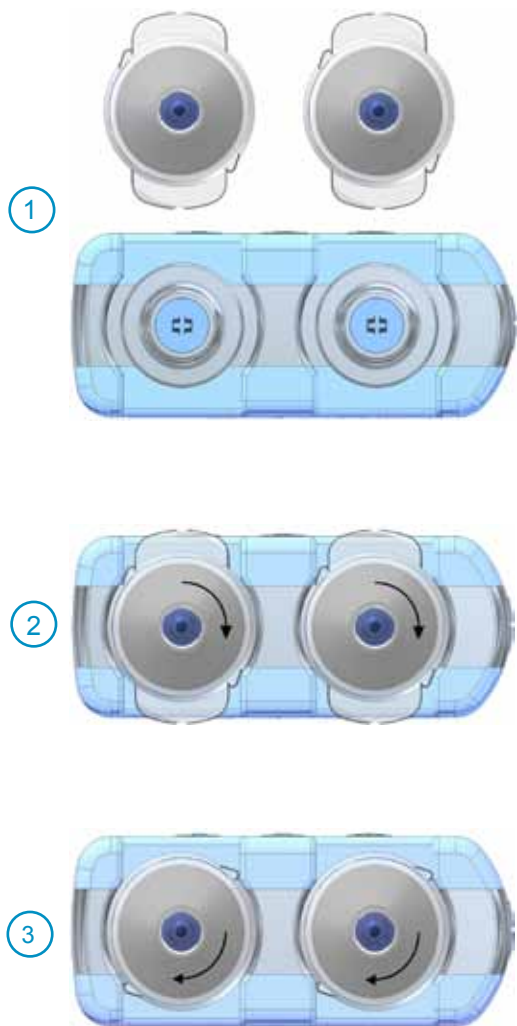
1. Screw the needles onto the *reservoirs* in a clockwise direction and remove the needles cover;
2. Fill the *reservoirs*, aspirating the liquid slowly and checking that the quantity of the drug does not exceed its capacity or any partial volume you may have set;
3. Screw the *Luer-Lock caps* (a) to the *reservoirs* and then unscrew the piston rods, turning it anticlockwise (b) with a reasonably rapid movement;
4. Insert the *reservoirs* into the pump; the pushers will be inserted into the pushers. Rotate its clockwise through 90° and its will click and engage with the pushers;
5. Insert the cones of the infusion set over the *reservoirs*.



INSERTION OF THE *RESERVOIRS* INTO THE PUMP

Insert the dedicated CRN *reservoirs* into the pump and engage its by rotating its 90° clockwise; a click confirms it has engaged.

Front view



WARNING**1 - Before filling the *reservoir***

Unscrew and screw back the piston rod to facilitate its unscrewing after you have filled the *reservoir*.

2 - Filling the *reservoir*

The liquid must be aspirated slowly.

Do not fill the *reservoir* more than the maximum level allowed of 20 ml.

The piston rod must be unscrewed with a reasonably rapid movement.

3 - Inserting the *reservoir* into the pump

To avoid any leakage of the drug while the *reservoir* is being inserted into the pump, you can use the infusion set, as an alternative to the *Luer-Lock* cap indicated on page 49.

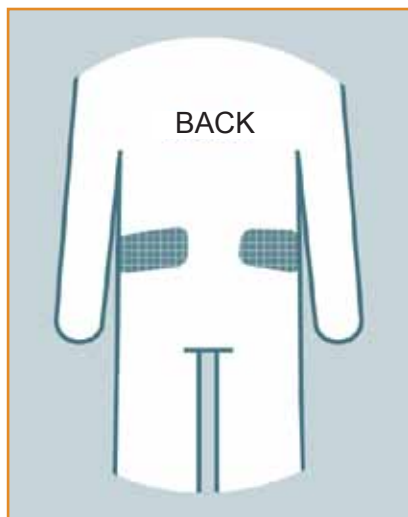
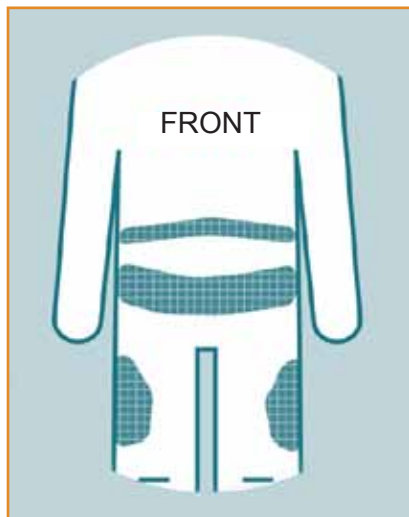
When making the connection, avoid exerting excessive pressure on the *reservoir* walls, because this could cause liquid to leak past the piston rings.

While filling the *reservoir* and inserting it into the pump, a small leakage might occur between the first and second rings on the rubber piston. This does not compromise either the correct working of the *reservoir* or the delivery of the drug.



INFUSION SITES

The figures below indicate the recommended infusion sites. You are recommended to change the injection site after every infusion to avoid skin irritations.



PREPARING FOR THE INFUSION

Before preparing for the infusion, you are recommended to adopt the following precautions:

1. Wash your hands
2. Prepare a clean working environment.



WARNING



Always carry out the infusion in antiseptic conditions, to reduce the risk of infection to the minimum.

The images refer to the Neria™ infusion set from Unomedical, a company in the Convatec group.

Disinfect the infusion site following the instructions of the relevant medical personnel. Ensure that the area of the infusion site is dry before inserting the subcutaneous needle.



Connect the infusion set to the *reservoirs*.



Hold the infusion set by the wings. Prime the infusion line manually or use the priming function of the pump. Ensure there are no air bubbles in the infusion line.

WARNING



When you are priming the infusion line and are preparing to insert the needle below the skin, hold the set with the needle pointing downwards to ensure that none of the drug can come into contact with the protecting adhesive paper.



Remove the protective adhesive paper.



Remove the needle cover, extracting it with care, before inserting the needle.

WARNING



Be careful not to touch the Neria™ needle when you remove the protection.



It is important to lift a fold of skin, to reduce the risk of positioning the needle in a muscle. Pinch the skin with your fingers at the chosen infusion site before inserting the needle, which you do by taking the holding wings of the infusion set with the other hand and inserting the needle vertically.



WARNING



Do not administer immunoglobulins intravenously; if they are accidentally administered to a blood vessel or capillary the patient could suffer an anaphylactic shock or thromboembolic events. Always check this before continuing with an infusion.



Press firmly on the adhesive to fix it to the skin. Check the infusion site frequently to ensure that the needle remains in the correct position. Repeat the above instructions for the second infusion site.

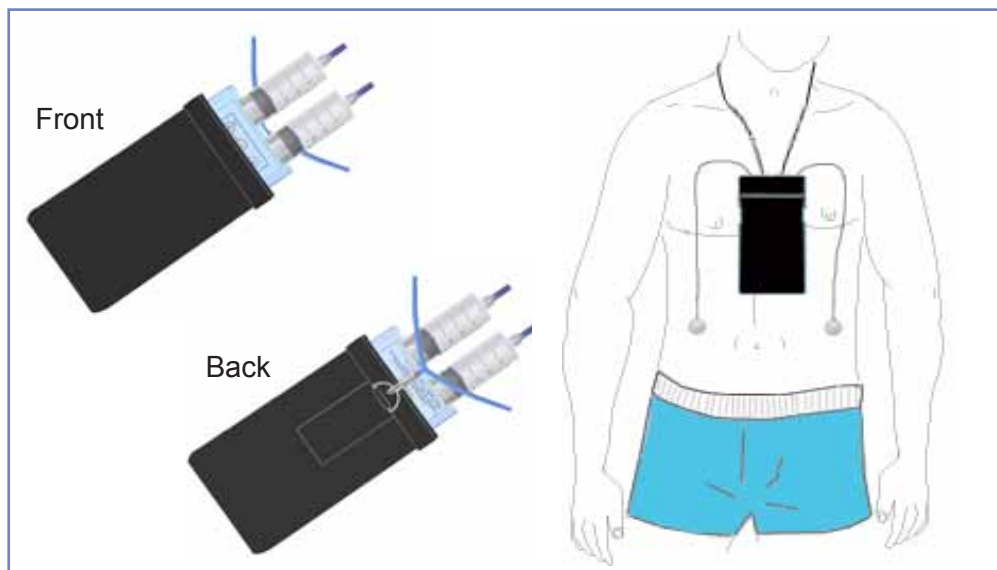


HOW TO USE THE SUPPLIED STANDARD EQUIPMENT

The following figures give an indication of how to use the standard equipment supplied with the pump.

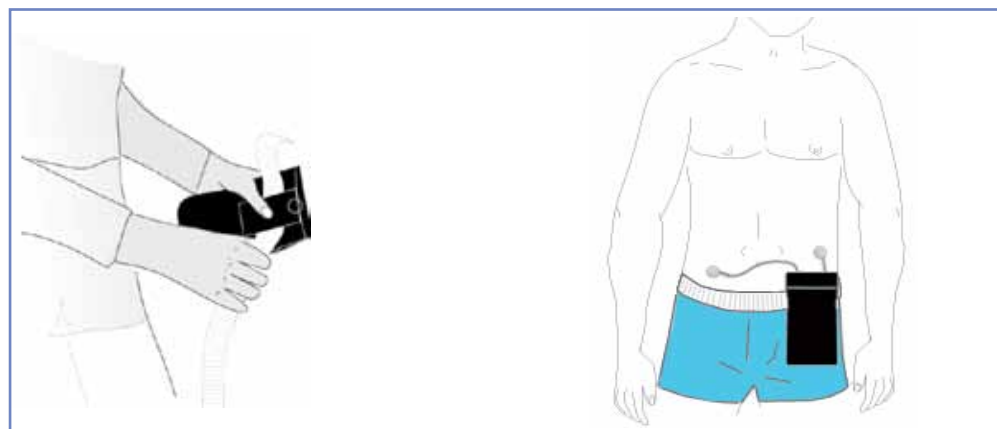
PUMP CARRIED AROUND THE NECK

The pump worn with a supporting cord and a fabric pouch.



PUMP ATTACHED AT THE WAIST

The pump worn with an elastic belt and a fabric pouch.





GENERAL WARNINGS

The device can be damaged by water, so it must not be kept on while in the bath or the shower, etc. If the device accidentally gets wet, (for example, by drops of the drug, or overnight bedwetting), you must ensure it is checked by CANÈ S.p.A. Customer Support Service.

The device must be kept away from:

- Sources of heat (radiators, gas rings, stoves, etc.)
- Direct sunlight
- Strong electro-magnetic fields (magnets, loudspeakers, mobile devices) - details are given in APPENDIX 6.
- Ionising radiation
- Ultrasound devices
- MRI devices.

The device does not need sterilising.

Do not freeze the CRN *reservoir* with the drug still in it.

The device must not be placed in a fridge or freezer.

The device must not be placed in an oven or microwave oven.

Reservoirs, infusion sets, needles, filters and all consumable materials must be disposed of in an appropriate way, using the appropriate containers.

If you do not observe the above warnings, the device could malfunction, with potentially serious consequences for the user.

MANUAL UPDATES

The version and the date of publication of this User Manual are given on every page. When a year has passed between the publication date (given on page 3) and the use of the product, the doctor should contact CANÈ S.p.A. to determine if a more recent version of the manual has been published.

MAINTENANCE

The technical characteristics of the device make it extremely simple to maintain.

If the device is damaged, you are recommended to have it checked by the CANÈ S.p.A. Customer Support Service, before re-using it.

The external surfaces can be cleaned with a lightly dampened soft cloth, using a mild detergent or disinfectant.

GENERAL WARNINGS



- Do not immerse the pump in detergent solutions or water.
- Avoid getting liquids inside the pump. If the device gets wet, immediately try to dry it with absorbent paper.
- Do not clean the pump with acetone, solvents or abrasive detergents.
- Do not sterilise the pump.

STORAGE

If the device is not used for more than one or two months, you are recommended to remove the battery and put the pump away in its case in a dry place at room temperature.

DISPOSAL

At the end of the expected life of the pump, contact the CANÈ S.p.A. Customer Support Service, which will provide you with instructions about the disposal of the device.

Reservoirs, infusion sets, needles, filters and all consumable materials must be disposed of in an appropriate way, using the appropriate containers.

EXPECTED PUMP LIFE

The pump is expected to last for 4 (four) years from its purchase date. For safety reasons you should not continue to use it after this period.

SUPPORT

The device must only be repaired by CANÈ S.p.A.'s Customer Support Service. Before sending the device you are advised to contact:

- **Customer Support Service**

CANÈ S.p.A. Medical Technology

Via Cuorgnè, 42/a

10098 Rivoli (Turin) - Italy

Tel. +39.011.9574872

Fax +39 011 959 8880

- **CANÈ S.p.A. On Line**

Internet: www.canespa.it - E-mail: service@canespa.it

GUARANTEE

With this guarantee, CANÈ S.p.A. guarantees the product from any material or manufacturing defects for a period of 2 (TWO) YEARS from the original date of purchase.

If, in the course of this guarantee period, any material or manufacturing defects are identified, CANÈ S.p.A. will repair or substitute the defective components according to the terms and conditions herein, without any charge for labour or parts; the Customer is responsible for the costs of sending the pump to the CANÈ S.p.A. Customer Support Service.

CANÈ S.p.A. reserves the right to vary the characteristics or model of its devices, without being under any obligation to make corresponding modifications to devices already manufactured and sold.

Conditions:

1. The guarantee is valid only if the defect is reported within the period of the guarantee.

2. This guarantee does not extend to any costs and/or defects following modifications or adaptations made to the product, without prior written authorisation by CANÈ S.p.A.

CANÈ S.p.A. disclaims all liability either to the purchaser or to third parties for damage that occurs to persons or things as a result of improper operation of the device, for uses of the device for which it was not intended and for the non-observance of the instructions provided in the instruction manual. The purchaser undertakes to indemnify CANÈ S.p.A. from any claims by third parties with respect to the above.

3. This guarantee is not valid if the model number and serial number of the product have been modified, erased, removed or have in any way made illegible.

4. The following are excluded from the guarantee:

- Periodic maintenance
- Damage consequent to improper use, including but not limited to:
 - Incorrect power supply
 - Use of the product for purposes other than those for which it is designed
 - Repairs performed by unauthorised personnel or by the Customer
- Accidental and unintentional events, such as liquid spills and falls
- Natural events and malicious or negligent acts
- The standard equipment supplied with the pump.

5. CANÈ S.p.A. undertakes to perform repairs on the device for a period of not more than 4 (four) years from the date of purchase.

After that period, CANÈ S.p.A. has no further obligations to make repairs. La CANÈ S.p.A. disclaims all liability either to the purchaser or to third parties for damage that occurs to persons or things as a result of the use of the device after 4 (four) years from the date of purchase.

6. After the guarantee period is expired, support will be provided by CANÈ S.p.A. with the customer bearing the subsequent costs of replaced parts, labour and transport in effect at the time.

7. The company declines all responsibility towards the patient and/or third parties for any health problems and/or difficulties arising during any period in which the device is returned to CANÈ for technical assistance.

8. The company declines all responsibility towards the patient and/or third parties for any difficulties or delays regarding the shipment of the device.

DECLARATION OF CONFORMITY

CE
0476

CANÈ S.p.A., with its registered offices in Via Cuornè, 42/a 10098 Rivoli (Turin) - Italy, manufacturer of the **CRONO TWIN** electro-medical ambulatory infusion drug pump via *reservoir*.



Serial No.








declares that the device conforms to the essential requirements of Appendix I of Directive 93/42/EEC, modified by Directive 2007/47/EEC, as per certificate MED 9813 provided by the Notifying Body No. 0476 according to Appendix II of the same Directive and is released to the market in compliance with the corresponding laws of the individual European member states.

Rivoli, 08/03/2012

The Chairman

APPENDICES








ICONS USED ON THE PUMP

SN	Serial No. of the pump
IP 4X	<p>IP protection rating</p> <p>1st figure (protection against entrance of solids) = 4 protection from solid objects larger than 1 mm.</p> <p>2nd figure (protection against entrance of liquids) = X no protection.</p>
 0476	CE marking
	<p>Electro-medical device</p> <p>Electrical classification: Class I, Type BF.</p>
	Warning: read instructions before use
 	<p>Waste separation of electric and electronic equipment</p> <p>Pursuant to article 13 of Legislative Decree 151 of 25 July 2005 “Implementation of the Directives 2002/95/EC, 2002/96/EC and 2003/108/EC concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment, as well as the disposal of waste.”</p>

The symbol of the crossed out waste bin on the product and its packaging indicates that at the end of its useful life, the product must be disposed of separately from other waste. Sorted waste disposal of products at the end of their useful life is organised and managed by the manufacturer. Users wishing to dispose of this device must therefore contact the manufacturer (or the appropriate local distributor) and follow the system which has been devised to allow for the sorted materials disposal of devices at the end of their useful lives. A proper sorted collection for devices destined for recycling, treating and environmentally compatible disposal, helps reduce the potentially negative impacts on the environment and health and facilitates the re-use or recycling of the materials from which the device is constructed. The illegal disposal of a product is punishable according to the laws currently in force.

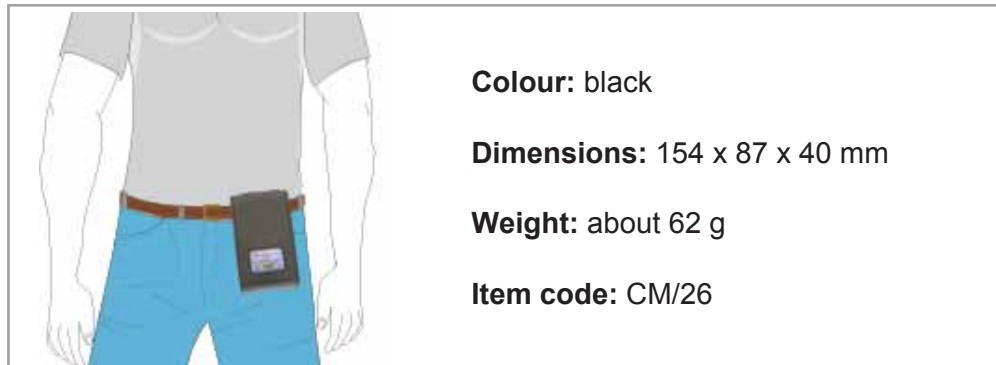
Note: The symbol displayed on the product label is, for obvious reasons of space, reduced and simplified with respect to the specifications in the reference standard CENELEC EN50419.

ICONS USED ON THE *RESERVOIR* BLISTER PACK

	Read the instructions
CE 0123	CE marking
	Recyclable
	Use only once
	Non-pyrogenic
	Keep dry
	Keep away from sunlight
	Expiry date
STERILE EO	Sterilised with ethylene oxide
PP	Polypropylene
LOT	Batch code
REF	Reference No.
NEEDLE	Needle size

OPTIONAL ACCESSORIES AVAILABLE ON REQUEST

Vertical leatherette pouch, similar to a mobile phone pouch.



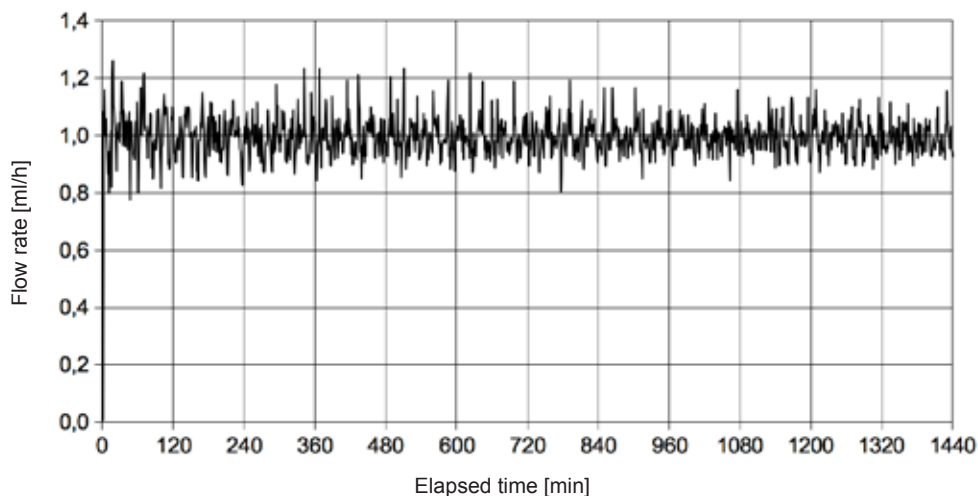
PRECISION TEST

The tests have been performed according to IEC 60601-2-24, Electro-medical devices, Part 2: Particular requirements for the safety of infusion pumps and controllers. The following graphs show the precision of the pump during the drug administration.

1.1 – Start-up flow

- Flow rate setting: 1 ml/h.

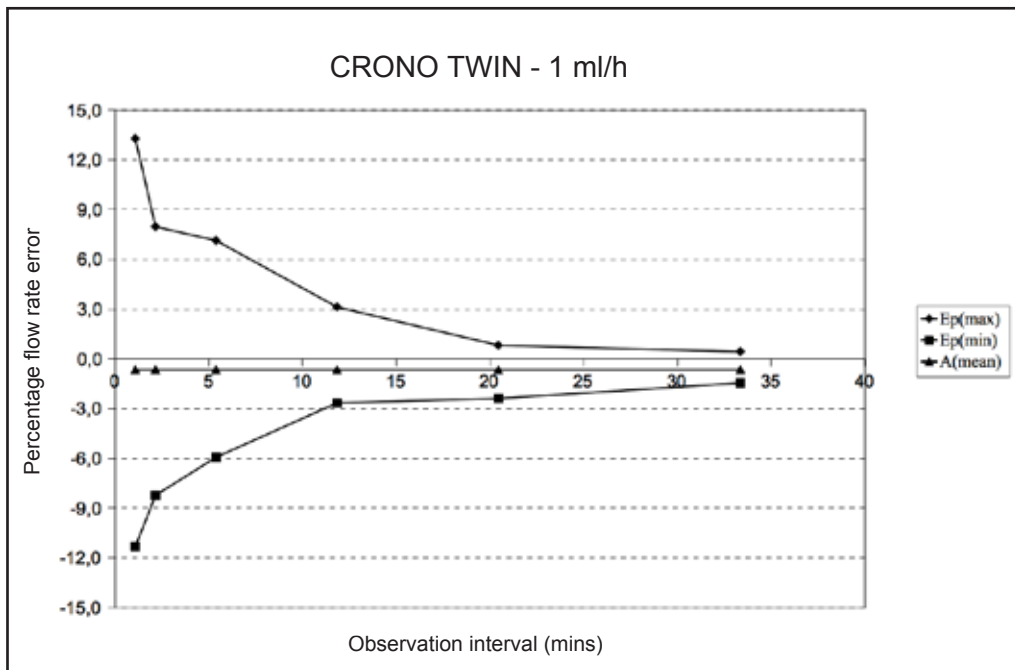
CRONO TWIN - 1 ml/h



TRUMPET CURVE

1.2 - Flow rate error (trumpet curve)

- Flow rate setting: 1 ml/h.



The degree of precision can be different from the information in this manual, according to the type of accessories and extension tubes used in the administration line of the drug.

OCCCLUSION SIGNALLING TIME

The time needed to signal an occlusion is the interval between when the occlusion occurs and the detection of the occlusion by the pump. This value depends on the flow rate, because the lower the flow rate, the longer the pump will take to detect the occlusion.

The values given here consider the time needed jointly by the pump and the *reservoir* to signal the occlusion.

Flow rate	Occlusion signalling time
0.2 ml/h	About 22 hours
1 ml/h	About 3 hours
40 ml/h	About 5 minutes

WARNINGS



- The time needed to signal an occlusion is dependant on the flow rate, because the lower the flow rate, the longer will be the time needed by the pump to ascertain the presence of an occlusion condition.
- The time needed to signal the occlusion can increase if there is air in the line, if you are using catheters, filters and extension tubes of other dimensions, or in an elastic material, or when the line from the pump is connected to other devices.
- For patients who could suffer severe harm if there is an interruption in the administration of the drug by the pump, arrangements must be made for them to be under the strict supervision of a doctor who can take any immediate corrective action required.

POST-OCCLUSION BOLUS

When the occlusion alarm sounds, the pump has detected an excessive back pressure in the infusion line. This back pressure must be removed in order to avoid releasing a post-occlusion bolus, which might cause serious harm to the patient. The volume of a **CRONO TWIN** post-occlusion bolus, considering only the combined volume of a single pump and the reservoir, is about 1.3 ml.

WARNINGS



- The volume of the bolus dose released post occlusion can increase if there is air in the line, if you are using catheters, filters and extension tubes of other dimensions or of a softer material, or when the line from the pump is connected to other devices.
- After the occlusion alarm sounds, take any and all measures appropriate to avoid the administration of a post-occlusion bolus to the patient.
- Patients who might suffer severe harm from the accidental release of a post-occlusion bolus must receive adequate instructions and/or training from medical or paramedical personnel on how to proceed in such a situation.

ELECTRO-MAGNETIC COMPATIBILITY

The electro-magnetic compatibility tests were performed in compliance with the standards:

- IEC 60601-2-24:1998, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers.
- IEC EN 60601-1-2 Ed. 2, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance – collateral standard: Electro-magnetic compatibility – Requirements and tests.

Guide and declaration by the manufacturer - electro-magnetic emissions

The **CRONO TWIN** is designed to operate in the electro-magnetic environment specified below. The customer or user of the **CRONO TWIN** must ensure that it is operated in such an environment.

Emission test	Conformity	Electromagnetic environment - guide
RF Emissions CISPR11	Group 1	The CRONO TWIN uses RF energy only for its internal operation. As a consequence, its RF emissions are very low and would thus not be expected to cause any interference to electronic devices in the vicinity. The CRONO TWIN is designed for use in all environments, including domestic environments and those environments directly linked to the low voltage mains supplying residential buildings.
RF Emissions CISPR11	Class B	
IEC 61000-3-2 harmonic emissions	N/A	
IEC 61000-3-3 emissions in the event of voltage fluctuations or flicker	N/A	


Guide and declaration by the manufacturer - electro-magnetic immunity

The **CRONO TWIN** is designed to operate in the electro-magnetic environment specified below. The customer or user of the **CRONO TWIN** must ensure that it is operated in such an environment.

Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - guide
IEC 61000-4-2 electro-static discharge (ESD)	15 kV in air 8 kV on contact	15 kV in air 8 kV on contact	The flooring must be wood, concrete or ceramic. If the floor is covered in a synthetic material, the relative humidity must be at least 30%.
Electro-magnetic fields	400 A/m 50 and 60 Hz	400 A/m 50 and 60 Hz	

Guide and declaration by the manufacturer - electro-magnetic immunity

The **CRONO TWIN** is designed to operate in the electro-magnetic environment specified below. The customer or user of the **CRONO TWIN** must ensure that it is operated in such an environment.

Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - guide
Radiated immunity	80-2500 MHz 10V/m AM 80% 1 KHz	10V/m	Interference could occur in the vicinity of devices marked with the following symbol: 
	20-80 MHz 10V/m AM 80% 1 KHz	10V/m	

Recommended separation distance between mobile and portable radiocommunication devices and the **CRONO TWIN**.

The **CRONO TWIN** is designed to operate in an electro-magnetic environment in which radiated RF disturbances are under control. The customer or operator of the **CRONO TWIN** can help prevent electro-magnetic interference by ensuring a minimum distance between mobile and portable communication devices using RF (transmitters) and the **CRONO TWIN**, as recommended below, relative to the maximum output power of the radio-communication devices.

Maximum specified output power of transmitter (W)	Separation distance at the transmitter frequency (m)	
	150 kHz to 80 MHz	80 MHz to 800 MHz
0.01	1.2	0.12
0.1	3.8	0.38
1	12	1.2
10	38	3.8
100	120	12

REFERENCE DIRECTIVES

- **Directive 93/42/EEC of the Council.** Medical devices.
- **Legislative Decree No. 46, 24 February 1997.** Implementation of Directive 93/42/EEC concerning medical devices.
- **Directive 2007/47/EC of the European Parliament and of the Council.** Amending directives 90/385/EEC of the Council on the approximation of the laws of the Member States relating to active implantable medical devices, 93/42/EEC of the Council concerning medical devices and 98/8/EC concerning the placing of biocidal products on the market.
- **Legislative Decree No. 37, 25 January 2010.** Implementation of directive 2007/47/EC.

TECHNICAL STANDARDS

- **IEC EN 60601-1:2007-05.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance.
- **IEC EN 60601-1/EC:2010-05.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance.
- **IEC EN 60601-1-1:2003-06.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Safety requirements for electro-medical systems.
- **IEC EN 60601-1-2/A1:2006-10.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Electro-magnetic compatibility – Requirements and tests.
- **IEC EN 60601-1-2:2010-01.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance - collateral standard: Electro-magnetic compatibility – Requirements and tests.
- **IEC EN 60601-1-4:1997-08.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – 4. Collateral standard: Programmable medical electrical systems.
- **IEC EN 60601-1-4/A1: 2000-06.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Programmable medical electrical systems.
- **IEC EN 60601-1-8:2009-11.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Alarm systems - General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- **IEC EN 60601-2-24:2012-10.** Medical electrical equipment, Part 2: particular requirements for the safety of infusion pumps and controllers.
- **IEC EN 60529 1997-06.** Protection ratings provided by enclosures (IP Code).

- **IEC 62-108: 2000-05.** Guide to the maintenance of infusion pumps and control systems.
- **IEC EN 62353:2008-11.** Medical Electrical Equipment—recurrent test and test after repair of medical electrical equipment.
- **IEC 62-122: 2002-07.** Guide to acceptance testing and periodic maintenance of the safety and/or performance of medical devices powered by a specific power source.
- **IEC 62-143: 2007-05.** Table of correspondence between articles (clauses) in the publication IEC 60601-1:2006 and those of the 1988 edition of the same, and its subsequent modifications.
- **IEC EN 62304:2006-10.** Medical device software – Software life cycle processes.

INFORMATION

For further information on the **CRONO TWIN** pump, contact:

Customer Support Service

CANÈ S.p.A. Medical Technology

Via Cuorgnè, 42/a


10098 Rivoli (Turin) - Italy

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NOTES



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